SEP - 1 1999

K992535

Section 6 - 510(k) Summary of Safety and Effectiveness

6.1 Statement	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92
6.2 Submitter	Endius, Inc. 23 West Bacon Street Plainville, MA. 02762
6.3 Company Contact	Susan Finneran QA/ RA Manager 508-643-0983
6.4 Device Name	**Proprietary Name**: Endius Suction/Irrigation Instrument **Common Name:** Endoscopic Suction/ Irrigation Device **Classification Name:** Endoscope and Accessories
6.5 Predicate Legally Marketed Devices	EndoSI™ Suction/Irrigation Trumpet Valve and Accessories
6.6 Device Description	The Endius Endoscopic Irrigation/ Suction Device is intended to be used to irrigate and aspirate fluids during Endoscopic and open spinal Procedures and therefore to assist in the visualization. The device consists of a single –use disposable tubing set/trumpet valve which is intended to be attached to a re-usable suction/irrigation attachment.

6.7 Device Indications and Intended use

The Endius Suction /Irrigation Device is intended to be used to irrigate/aspirate fluids during Endoscopic and open spinal surgical procedures.

6.8 Substantial Equivalence

The Endius Endoscopic Spinal Access System is substantially equivalent to the EndoSI™ Suction/Irrigation Trumpet Valve and Accessories

Table of Substantial Equivalent Device Similarities

Device Name	**EndoSI™ Suction/Irrigation Device**	**Endius Suction/Irrigation Device**
Intended use	Irrigation and Aspiration of fluid during laparoscopic procedures	Irrigation and Aspiration of fluid during Endoscopic Spinal procedures.
Materials	PVC, ABS	PVC, ABS, Delrin
Sterilization Methods	Sterile components sterilized by gamma irradiation	Sterile components sterilized by gamma irradiation
Product Labeling	**Trumpet Valve:** Sterile, single use **Suction/Irrigation attachment:** Sterile,single use	**Trumpet Valve:** Sterile, single use **Suction/Irrigation attachment:** Non-Sterile, re-usable
Packaging	Sterile components packaged in Tyvek pouch	Sterile components packaged in Tyvek pouch

Applicant _____ Date 7/27/99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 1999

Ms. Susan Finneran
Manager, Quality Assurance and Regulatory Affairs
Endius, Inc.
23 West Bacon Street
Plainville, Massachusetts 02762

Re: K992535
Trade Name: Endius Suction/Irrigation Device
Regulatory Class: II
Product Code: KOG
Dated: July 28, 1999
Received: July 29, 1999

Dear Ms. Finneran:

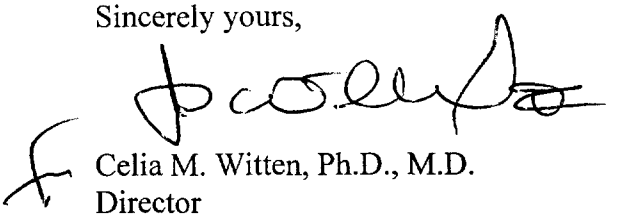
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K992535

510(k) Number (if known):

Device Name: Endius Suction /Irrigation Device

Indications for Use: The Endius Suction/ Irrigation Device is intended to be used to irrigate and aspirate fluid during Endoscopic and open spinal procedures

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992535